

REMARKS

Currently claims 1-27 are pending, with claims 5-16 and 19-26 withdrawn from prosecution by the Examiner pursuant to 35 U.S.C. § 121. Upon entry of the forgoing amendment, claims 4, 8, 9, 13-16 and 19-27 are canceled without disclaimer of, or prejudice to, the subject matter contained therein. Claims 17 and 18 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 4 and 27 stand as objected to, and claims 1-3 are allowed.

Claim 17 is amended to incorporate the limitations of claim 27. Also, withdrawn method claim 5 is amended to include the limitations of product claims 1 and 8. It is believed that as amended, method claims 5-7 and 10-12 include the limitations of the allowable composition claims and thus, may be rejoined for immediate allowance.

Support for the amendment of the claims is provided by the claims as originally filed, and the specification at page 20, lines 14 to 21, and FIG. 7 and related text, showing use of the primers of SEQ ID NO: 7 and 8 to specifically detect *H. capsulatum* (e.g., *H. capsulatum* H1 and H2), as opposed to other fungi (e.g., two strains of *B. dermatitidis* B1 and B2; *C. neoformans* (Cn); *Aspergillus nidulans* (Ani); and *Aspergillus niger* (Ang)). Accordingly no new matter is added by the amendment of the specification or the claims.

Election

Applicants hereby affirm the election of Group I, claims 1-4, 17-18 and 27, and the species of SEQ ID NO: 1, and corresponding primers SEQ ID NO: 7 and SEQ ID NO: 8.

Priority

The Examiner asserted that the disclosure of the prior-filed Application No. 60/428,135, fails to provide adequate support or enablement under 35 U.S.C. § 112, first paragraph, for one or more claims of the application. Thus, the Examiner stated:

Provisional 60/428,135 describes the *H. capsulatum* chitin synthase G gene and fails to provide adequate support or disclose the *H. capsulatum* chitin synthase 2 gene as required by the claims. As such the priority date of record for claims for the instant application is 11/21/2003.

Office Action at page 3.

Applicants respectfully assert that the *H. capsulatum* chitin synthase G as described in provisional patent application 60/428,135 is the same as the chitin synthase 2 described and claimed in the instant patent application. The Applicants originally used the nomenclature chitin synthase G to reflect the similarity of the isolated protein with *Coccidioides* chitin synthase G, but subsequently decided to name the gene chitin synthase 2. The *C. immitis* name was initially used due to the significant homology between Applicants' novel cloned gene from *H. capsulatum*, and the *C. immitis* chitin synthase G sequences obtained from the NCBI database, as there were no complete *H. capsulatum* sequences in the database at that time. At the time, however, efforts were underway to clarify the nomenclature for the various chitin synthase genes and protein isomers such that when Applicants entered the genomic sequencing data results into the database, it was decided to name the gene *H. capsulatum* chitin synthase 2 gene (*chs2*). Applicants present herein as Attachment A, a peptide sequence alignment of a published *C. immitis* chitin synthase G (Subject) to the *H. capsulatum* chitin synthase 2 (Query) of the application, illustrating the homology at the protein level between the two sequences.

Also, Applicants respectfully note that the nucleic acid sequences for the chitin synthase cDNA presented in provisional patent application 60/428,135 and the instant application (SEQ ID NO: 9 in both applications) are identical. Also, the genomic sequences (SEQ ID NO: 10 in both applications), and the protein sequence (FIG. 6 of 60/428,135; FIG. 4 and SEQ ID NO: 23 of the instant application) are identical. Thus, the protein and nucleic acid described as *H. capsulatum* chitin synthase G in provisional application 60/428,135 is identical to the protein and nucleic acid described in the instant application as *H. capsulatum* chitin synthase 2. Further substantiating the identity of these two genes, is the identical sequence and location of the introns (see FIG. 2 of both applications) as well as the identical sequence of the primers (FIG. 4 and SEQ ID NOs: 7 and 8 of provisional application 60/428,135; FIG. 6 and SEQ ID NOs: 7 and 8 of the instant application) used for amplification of intron 1 of the chitin synthase gene.

Also shown in provisional patent application 60/428,135 is the ability of the primers of SEQ ID NO: 7 and 8 to specifically detect *H. capsulatum* (e.g., *H. capsulatum* H1 and H2), as opposed to other fungi (e.g., two strains of *B. dermatitidis* B1 and B2; *C.*

neoformans (Cn); *Aspergillus nidulans* (Ani); and *Aspergillus niger* (Ang)). This data is shown as FIG. 5 of provisional application 60/428,135 and FIG. 7 of the instant application; the figures are identical.

For at least these reasons, Applicants respectfully assert that provisional patent application provides adequate support and disclosure of *H. capsulatum* chitin synthase 2 as required under 35 U.S.C. § 112, first paragraph, and respectfully request that the priority date of November 21, 2002 (i.e., the filing of provisional application 60/428,135) be instated for this application.

The Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph, Is Traversed Or Rendered Moot

The Examiner rejected claims 17 and 18 as not enabled under 35 U.S.C. § 112, first paragraph. Thus the Examiner stated:

[W]hile the specification teaches SEQ ID No. 1-10 as the gene, introns and primers to chitin synthase 2 gene of *H. capsulatum*, the claims encompass wild-type, mutant, and variant chitin synthase sequences (including other chitin synthase other than chitin synthase 2) that have not been taught or described by the specification. . . . The claims encompass any 21 consecutive nucleic acid sequence of any chitin synthase and the specification does not define “any” chitin synthase gene other than the chitin synthase 2 gene defined by SEQ ID No. 9 and 10.

Office Action at pages 4-5.

The Examiner also rejected claims 17 and 18 and 27 as not satisfying the written description under 35 U.S.C. § 112, first paragraph. Thus the Examiner stated:

While the specification teaches SEQ ID NO 1, 7-8 the specification provides insufficient written description to support the broad genus encompassed by the claims.

...

The amendment to the claims 17, “isolated nucleic acid consisting of at least 21 consecutive nucleic acid” changes the scope of the claim and recitation of at least 21 consecutive nucleic acid molecules of any intron of any *H. capsulatum* chitin synthase gene is not supported in the specification and raises the issue of new matter. The specification teaches at least 8 consecutive nucleotides of SEQ ID No. 1-6 (see page 15, lines 1-5) and teaches primers of SEQ ID No. 1 that are 21 nucleotides long,

however the specification does not teach 21 consecutive nucleic acid molecules of “any” intron of “any” *H. capsulatum* chitin synthase gene.

Office Action at pages 5 and 7.

The Examiner further noted that claim 27 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Office Action at page 8.

Claim 17 is amended to include the limitations of claim 27, and claim 27 is canceled. Thus, as amended, claim 17 recites: (a) one or more containers comprising an isolated nucleic acid molecule selected from the group consisting of a fragment of SEQ ID NOS: 1-6 consisting of 21 or more consecutive nucleotides of SEQ ID NOS: 1-6, or 21 or more consecutive nucleotides of the complement of SEQ ID NOS: 1-6; and (b) at least one separate container comprising an isolated nucleic acid molecule comprising a chitin synthase intron DNA selected from the group consisting of a nucleic acid molecule comprising the sequence of SEQ ID NOS: 1-6, or the complement thereof.

Thus, Applicants respectfully assert that as amended, claims 17 and 18 satisfy the written description and enablement requirements under 35 U.S.C § 112, first paragraph, and request that the rejection be withdrawn.

Double Patenting

The Examiner stated that claim 4 is a substantial duplicate of claim 1 under 37 C.F.R. § 1.75. Applicants have canceled claim 4, and thus respectfully assert that the objection has been rendered moot.

Rejoinder of Withdrawn Claims

Withdrawn process claims that depend from, or otherwise include all of, the limitations of an allowable product claim may be rejoined in accordance with the provisions of MPEP § 821.04, and such amendments will be entered as a matter of right if presented prior to allowance. Applicants have amended claims 5-7 and 10-12 for re-entry in the case. Applicants respectfully request reentry of the amended method claims

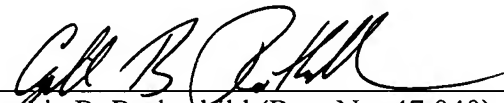
5-7 and 10-12 into the application and respectfully assert that the amended claims are in condition for immediate allowance.

CONCLUSION

In view of the foregoing amendment and remarks, each of the claims remaining in the application is in condition for immediate allowance. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the outstanding rejections. The Examiner is respectfully invited to telephone the undersigned at (336) 747-7541 to discuss any questions relating to the application.

Respectfully submitted,

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